

IN THE UNITED STATES DISTRICT COURT  
FOR THE NORTHERN DISTRICT OF WEST VIRGINIA

NOVARTIS PHARMACEUTICALS CORPORATION  
NOVARTIS CORPORATION, NOVARTIS AG,  
and NOVARTIS PHARMA AG,

Plaintiffs,

v.

CIVIL ACTION NO. 1:14cv111  
(Judge Keeley)

MYLAN INC., and MYLAN  
PHARMACEUTICALS, INC.,

Defendants.

SCHEDULING ORDER

On **February 19, 2015**, the parties filed their meeting report and proposed discovery plan. On March 5, 2015, the Court conducted a scheduling conference in this matter and, pursuant to Fed. R. Civ. P. 16(b), Fed. R. Civ. P. 26(f) and the Local Rules of Civil Procedure, as amended on July 20, 2010, **ORDERS** that the following table of dates and deadlines shall govern the further preparation of this case<sup>1</sup>:

TABLE OF DATES AND DEADLINES	
PLAINTIFF JOIN PARTIES OR AMEND PLEADINGS	April 10, 2015
DEFENDANT JOIN PARTIES OR AMEND PLEADINGS	April 10, 2015

---

<sup>1</sup> As noted in this Court's First Order and Notice Regarding Discovery and Scheduling, the report is considered advisory only. Accordingly, this Court adopts the proposed discovery plan of the parties only to the extent noted.

Novartis, etc., et al. v. Mylan, etc., et al.

1:14cv111

## SCHEDULING ORDER

OPENING EXPERT REPORTS	October 19, 2015
REBUTTAL EXPERT REPORTS	November 19, 2015
EXPERT DISCOVERY	February 29, 2016
DAUBERT MOTIONS	March 31, 2016
DAUBERT RESPONSE	April 29, 2016
DAUBERT HEARING	May 31, 2016 10:30 a.m.
COMPLETION OF FACT DISCOVERY	October 8, 2015
PRODUCTION OF DOCUMENTS	
DEFENDANTS ANDA PRODUCTION	March 15, 2015
PLAINTIFFS' FIRST PRODUCTION	March 31, 2015
DEFENDANTS' FIRST PRODUCTION	March 31, 2015
PLAINTIFFS' SECOND, THIRD, AND FOURTH PRODUCTION	April 30, 2015
DEFENDANTS' SECOND PRODUCTION	April 30, 2015
PLAINTIFFS PRODUCE ALL LITIGATION AND DISCOVERY FROM THE "PRIOR LITIGATION (a defined term)	April 30, 2015
PLAINTIFFS PRODUCE IN-SUIT PATENTS AND ASSOCIATED PROSECUTION HISTORIES; IND NO. 58,544; NDA NO. 21-882	March 15, 2015
MARKMAN EVENTS	
IDENTIFY CLAIM TERMS FOR CONSTRUCTION	May 12, 2015
EXCHANGE PROPOSED CONSTRUCTIONS, INCLUDING INITIAL IDENTIFICATION OF INTRINSIC AND EXTRINSIC EVIDENCE TO BE RELIED UPON	May 26, 2015

Novartis, etc., et al. v. Mylan, etc., et al.

1:14cv111

## SCHEDULING ORDER

OPENING CLAIM CONSTRUCTION BRIEFS	June 8, 2015
RESPONSE CLAIM CONSTRUCTION BRIEFS	June 22, 2015
CLAIM CONSTRUCTION HEARING	June 30, 2015 10:30 a.m.
DISPOSITIVE MOTIONS	June 30, 2016
RESPONSE TO DISPOSITIVE MOTIONS	July 15, 2016
REPLY TO DISPOSITIVE MOTIONS	July 29, 2016
PRETRIAL MEMORANDUM	September 9, 2016
PLAINTIFF'S FINAL LIST OF WITNESSES AND EXHIBITS	September 28, 2016
DEFENDANT'S FINAL LIST OF WITNESSES AND EXHIBITS	September 28, 2016
PLAINTIFF'S INTERROGATORIES AND DEPOSITIONS TO BE USED AT TRIAL	September 28, 2016
DEFENDANT'S INTERROGATORIES AND DEPOSITIONS TO BE USED AT TRIAL	September 28, 2016
STIPULATION OF FACTS	September 28, 2016
PROPOSED EXPERT WITNESS BIOGRAPHICAL SKETCHES	September 28, 2016
DESIGNATION OF JOINT EXHIBITS	September 28, 2016
PRETRIAL CONFERENCE	September 22, 2016 10:30 a.m.
TRIAL DATE	October 3, 2016 9:00 a.m. first

1. **JOINDER AND AMENDMENTS:** Motions to join additional parties, motions to amend pleadings, as well as any similar motions, by the plaintiff shall be filed by **April 10, 2015**. Motions

Novartis, etc., et al. v. Mylan, etc., et al.

1:14cv111

---

SCHEDULING ORDER

---

to join additional parties, motions to amend pleadings, as well as any similar motions, by the defendant shall be filed by **April 10, 2015.**

2. **EXPERT REPORTS/DISCLOSURES:** The plaintiffs and defendants shall file their opening expert reports and disclosures of information required by Fed. R. Civ. P. 26(a)(2)(A) and (B) for that issue to all other parties or their counsel no later than **October 19, 2015.** All parties shall provide the disclosures required by Fed. R. Civ. P. 26(a)(2)(A) and (B) if the evidence is intended solely to contradict or rebut evidence on the same issue identified by another party under Fed. R. Civ. P. 26(a)(2)(B), no later than **November 19, 2015.**

If further responsive expert reports are necessary, defendant may move the court for a further opportunity, within ten (10) days of its receipt of plaintiffs' rebuttal report.

The disclosures described in Fed. R. Civ. P. 26(a)(2)(B) shall not be required of physicians and other medical providers who examined or treated a party or party's decedent unless the physicians or medical providers will render an expert opinion in the case.

Novartis, etc., et al. v. Mylan, etc., et al.

1:14cv111

---

SCHEDULING ORDER

---

3. **DAUBERT MOTIONS, RESPONSE, HEARING DATE:** *Daubert* motions shall be filed by **March 31, 2016**. Any such motions must be supported by a memorandum at the time the motion is filed with the Clerk. Response to such motions shall be delivered to the Clerk with copies served upon opposing counsel on or before **April 29, 2016**. No reply to the response shall be filed. A hearing on *Daubert* motions will be held on **May 31, 2016 at 10:30 a.m.** at the Clarksburg, West Virginia point of holding court. By joint stipulation, the parties may choose to forego a hearing and submit *Daubert* motions for decision on the briefs.

4. **FACT AND EXPERT DISCOVERY:** All fact discovery shall be completed by **October 8, 2015**. All expert discovery shall be completed by **February 29, 2016**. "Completed discovery" as used in Fed. R. Civ. P. 16(b) means that, within the time limits set, all discovery, objections, motions to compel, and all other motions and replies relating to discovery in this civil action have been filed and the party objecting or responding has had sufficient time under the Federal Rules of Civil Procedure to make responses. The term "all discovery" in the preceding definition of "completed discovery" includes the disclosures required by Fed. R. Civ. P.

Novartis, etc., et al. v. Mylan, etc., et al.

1:14cv111

---

SCHEDULING ORDER

---

26(a)(1) and (2), but does not include the disclosures required by Fed. R. Civ. P. 26(a)(3).

Parties have a continuing obligation to supplement their responses beyond the discovery cut-off date, as provided in Fed. R. Civ. P. 26(e). The parties should refer to L.R. Civ. P. 5.01, L.R. Civ. P. 26.01 -26.04, L.R. Civ. P. 33.01, L.R. Civ. P. 34.01, L.R. Civ. P. 36.01, and L.R. Civ. P. 37.01 - 37.02 for further instructions on discovery practice.

The conduct of any discovery which would require a later time limit shall be permitted only on the order of the Court or by filed stipulation of the parties, and only in cases that will not be delayed for trial thereby.<sup>2</sup> The parties should be aware that a stipulation to the continuance of discovery anticipates no discovery disputes and, therefore, this Court will not hear discovery disputes arising during the stipulated continuance.

---

<sup>2</sup> Extension of the discovery deadline does not change the other deadlines set forth herein nor shall it be a basis for seeking extension of those deadlines. In particular, the deadline for dispositive motions generally cannot be changed without affecting the trial date. In considering to extend discovery, the parties should give thought as to any possible impact on contemplated dispositive motions.

Novartis, etc., et al. v. Mylan, etc., et al.

1:14cv111

---

SCHEDULING ORDER

---

5. PRODUCTION OF DOCUMENTS:

Novartis's First Production: On or before **March 31, 2015**, plaintiffs shall produce the patents-in-suit and associated prosecution histories; Investigational New Drug Application ("IND") No. 58,544; and New Drug Application ("NDA") No. 21-882;

Mylan's First Production: On or before **March 31, 2015**, defendants shall produce Abbreviated New Drug Application ("ANDA") No. 206585, including any correspondence with the FDA concerning ANDA No. 206585. Defendants shall also produce any agreements for an entity other than Mylan to manufacture, sell, or offer to see the product described in ANDA No. 206585 upon approval;

Novartis's Second Production: On or before **April 30, 2015**, Novartis shall produce, to the extent permitted by any applicable protective order or local law, and to the extent such documents remain within Novartis's possession, custody or control, on or before April 30, 2015, Novartis shall produce the following litigation documents filed or served by Novartis in the First Litigation: Novartis's submissions to the Court (including pleadings, letters, motions, briefs, declarations and exhibits); Novartis's responses to written discovery requests concerning issues other than infringement of the patents-in-suit; expert

Novartis, etc., et al. v. Mylan, etc., et al.

1:14cv111

---

SCHEDULING ORDER

---

reports (and exhibits) served by Novartis concerning validity of the patents-in-suit, and transcripts of depositions (with exhibits, signature pages and any errata sheet(s)) of Novartis's fact and expert witnesses in the First Litigation. To the extent that Novartis cannot produce any such document described herein because it was designated by Defendants under the applicable protective order as containing confidential information, Novartis shall produce on April 30, 2015, a log identifying such documents so that Mylan may seek consent from Defendants regarding whether such documents may be produced in this action;

Novartis's Third Production: On or before **April 30, 2015**, to the extent permitted by any applicable protective order or local law, and to the extent such documents remain within Novartis's possession, custody or control, on or before April 30, 2015, Novartis shall produce the following litigation documents filed or served by Defendants in the First Litigation: Defendants' submissions to the Court (including pleadings, letters, motions, briefs, declarations and exhibits); Defendants' responses to written discovery requests concerning issues other than infringement of the patents-in-suit; expert reports (and exhibits) served by Defendants concerning validity of the patents-in-suit,

Novartis, etc., et al. v. Mylan, etc., et al.

1:14cv111

---

SCHEDULING ORDER

---

and transcripts of depositions (with exhibits, signature pages and any errata sheet(s)) of Defendants' expert witnesses in the First Litigation. To the extent that Novartis cannot produce any such document described herein because it was designated by Defendants under the applicable protective order as containing confidential information, Novartis shall produce on April 30, 2015, a log identifying such documents so that Mylan may seek consent from Defendants regarding whether such documents may be produced in this action;

Novartis's Fourth Production: On or before **April 30, 2015**, to the extent permitted by any applicable protective order or local law, and to the extent such documents remain within Novartis's possession, custody or control, on or April 30, 2015, Novartis shall produce all non-privileged documents that Novartis produced in response to requests for production served pursuant to Fed. R. Civ. P. 34 in the First Litigation, including supplemental documents sufficient to show (1) sales and revenues of EXJADE<sup>®</sup>, and (2) marketing and promotional EXJADE<sup>®</sup> materials provided to healthcare providers that Novartis has generated since the end of the First Litigation; and

Novartis, etc., et al. v. Mylan, etc., et al.

1:14cv111

---

SCHEDULING ORDER

---

*Mylan's Second Production:* On or before **April 30, 2015**, to the extent not otherwise produced as part of Mylan's First Production, Mylan shall produce: (1) any and all ANDAs submitted by Mylan seeking approval to market a generic version of EXJADE® (deferasirox) tablets, for oral suspension ("EXJADE® ANDA"); (2) any and all certifications or statements under 21 U.S.C. § 355(j)(2)(A)(vii) & (viii) prepared or submitted in connection with an EXJADE® ANDA, including related correspondence; (3) any and all documents submitted to the FDA in support of each EXJADE® ANDA, certification, or statement; (4) any and all studies or testing conducted during development of any proposed generic version of EXJADE® (deferasirox) tablets, for oral suspension, regardless of whether such studies and testing were submitted to the FDA; (5) any and all projections of approval or timelines for selling any proposed generic version of EXJADE® (deferasirox) tablets, for oral suspension; (6) any and all projections of sales and revenues for any proposed generic version of EXJADE® (deferasirox) tablets, for oral suspension; and (7) any and all documents that Mylan intends to support its claims or defenses.

6. **CLAIM CONSTRUCTION ISSUE IDENTIFICATION:** On or before **May 12, 2015**, the parties shall identify and exchange a list of

Novartis, etc., et al. v. Mylan, etc., et al.

1:14cv111

---

SCHEDULING ORDER

---

those claim terms that they believe will likely be disputed and require construction. On or before **May 26, 2015**, the parties shall exchange their proposed claim constructions, including identification of all intrinsic and extrinsic evidence to be relied upon.

7. **CLAIM CONSTRUCTION PRODUCTION/ANDA:** The plaintiffs shall produce all litigation documents and discovery from the Prior Litigation (a defined term in the parties Rule 26(f) report), including, but not limited to, pleadings, discovery responses, expert reports, deposition transcripts and accompanying exhibits, pretrial submissions and briefs, by no later than **April 30, 2015**. Plaintiffs shall produce the patents-in-suit and associated prosecution histories; IND No. 58,544, and NDA No. 21-992, by no later than **March 15, 2015**.

Defendants shall produce ANDA No. 206585, including any correspondence with the FDA or agreements with an entity other than defendant to manufacture, sell, or offer to sell the product described in ANDA No. 206585.

8. **CLAIM CONSTRUCTION BRIEFING/HEARING:** The parties shall file their opening brief on or before **June 8, 2015**. Responsive claim construction briefs shall be filed no later than **June 22**,

Novartis, etc., et al. v. Mylan, etc., et al.

1:14cv111

---

SCHEDULING ORDER

---

2015. A hearing on claim construction will be held on **June 30, 2015 at 10:30 a.m.**, at the Clarksburg, West Virginia point of holding court.

9. **LIMITATIONS ON DISCOVERY**: The preemptive limitations on discovery (numbers of interrogatories, requests for admission, and depositions) set out in L.R. Civ. P. 26.01© apply to this case unless otherwise stipulated or ordered.

10. **DISPOSITIVE MOTIONS**: All dispositive motions, as well as deposition transcripts, admissions, documents, affidavits, and any other such matters in support thereof, shall be filed by **June 30, 2016**. Unless parties have obtained an early briefing schedule from the Court, all dispositive motions should be filed after the close of discovery.

Any such motion must be supported by a memorandum at the time the motion is filed with the Clerk. Memoranda in opposition to such motions shall be delivered to the Clerk with copies served upon opposing counsel on or before **July 15, 2016**. Any reply memoranda shall be delivered to the Clerk with copies served upon opposing counsel on or before **July 29, 2016**. All dispositive motions unsupported by memoranda will be denied without prejudice. See L.R. Civ. P. 7.02(a).

Novartis, etc., et al. v. Mylan, etc., et al.

1:14cv111

---

SCHEDULING ORDER

---

Factual assertions made in memoranda should be supported by specific references to affidavits, depositions or other documents made a part of the record before the Court. Copies of the supporting documents, or relevant portions thereof, should be appended to the memoranda. The parties may refer to L.R. Civ. P. 7.02, L.R. Civ. P. 12.02 and L.R. Civ. P. 78.01 for details on motion practice before this Court.

11. **PRETRIAL MEMORANDUM:** A pretrial memorandum shall be submitted to the Court not later than **September 9, 2016**. The pretrial memorandum shall contain at least those matters provided for under L.R. Civ. P. 16.04(b).

The pretrial memorandum shall contain for each party, a list of all witnesses who will be called at the trial:

- A. Each list of witnesses should include the witnesses' addresses and a statement of the general subject matter of their testimony. It is **NOT** sufficient to designate the witness simply "fact," "medical," or "expert." The list must also include an indication in good faith of those witnesses who **WILL** be called in the absence of reasonable notice to opposing counsel to the contrary and of those witnesses who **MAY** be called.
- B. This restriction does not apply to rebuttal witnesses or documents when necessity cannot be reasonably anticipated. Furthermore, in the case of expert witnesses, counsel shall certify that they have exchanged expert reports or have otherwise exchanged expert information. Expert witnesses

Novartis, etc., et al. v. Mylan, etc., et al.

1:14cv111

---

SCHEDULING ORDER

---

whose reports have not been furnished to opposing counsel will not be permitted to testify nor shall experts be permitted to testify to opinions not included in the reports timely furnished.

C. Except for good cause shown, the Court will not permit any witness to testify unless with respect to such witness there has been complete compliance with all provisions of this Order and prior court orders.

The witness lists submitted to this Court as part of the pretrial memorandum shall include all of a party's potential witnesses and exhibits and no party shall be permitted to add to these lists after the pretrial memorandum is submitted to the Court. Following the pretrial conference, this Court shall enter the final pretrial order which shall be modified only to prevent manifest injustice.

The pretrial memorandum shall further include that party's objections to witnesses, exhibits, interrogatories, and depositions proposed by the other party.

Any objection to interrogatories, depositions, witness, or exhibit lists shall include a copy of the exhibit where possible, and shall include an appropriate statement of authorities in support of the party's position. This paragraph does not apply to discovery materials that will be used at trial solely in cross-examination or for impeachment. Failure to comply with this

Novartis, etc., et al. v. Mylan, etc., et al.

1:14cv111

---

SCHEDULING ORDER

---

paragraph may constitute a waiver of objection or may result in the Court's denying any objection to the admission of an affected exhibit or witness.

12. **FINAL LIST OF WITNESSES AND EXHIBITS**: Pursuant to Fed. R. Civ. P. 26(a)(3), on or before **September 28, 2016**, plaintiff shall file with the Clerk a final list of those exhibits and witnesses that he or she actually intends to use or call at trial. Prior to that, he shall either forward copies of the proposed exhibits or make them available to all other counsel for examination. On or before **September 28, 2016** defendant shall file a list of proposed exhibits to be used and witnesses to be called at trial after having forwarded copies of them or having them available for examination to all other counsel. All exhibits shall be appropriately marked in numerical sequence (not lettered). Exhibit markers may be obtained from the Clerk.

By each of the dates set forth above, each counsel shall tender to the Clerk two sets (preferably in binders and on disk) of copies of the exhibits to be used at trial. These should be indexed for easy reference and each paper exhibit should be individually tabbed. One of the binders will be for the Court's use and the other is for use by the witness. Counsel should have their own

Novartis, etc., et al. v. Mylan, etc., et al.

1:14cv111

---

SCHEDULING ORDER

---

copy of each exhibit and should furnish opposing counsel with a copy of each exhibit. Original exhibits shall be submitted to the Clerk at trial and should not be tendered to the Clerk prior to trial.

13. **INTERROGATORIES AND DEPOSITIONS TO BE USED AT TRIAL:**

Pursuant to Fed. R. Civ. P. 26(a)(3), on or before **September 28, 2016**, plaintiff shall file with the Clerk any interrogatories, answers thereto, depositions, etc., specifying the appropriate portions thereto that plaintiff intends to offer in this case. Defendant shall do the same on or before **September 28, 2016**. Before designating these discovery materials, the parties shall meet and agree as to the elimination of all irrelevant and repetitive matter, and all colloquy between counsel in the depositions.

14. **STIPULATION OF FACTS:** Counsel are encouraged to meet and enter into stipulations of facts in this case and any such stipulation shall be reduced to writing, signed by counsel and filed with the Court and with opposing counsel by **September 28, 2016**.

Novartis, etc., et al. v. Mylan, etc., et al.

1:14cv111

---

SCHEDULING ORDER

---

15. BIOGRAPHICAL SKETCHES: Biographical sketches of any proposed expert witnesses shall be filed with the Court and with opposing counsel by **September 28, 2016**.

16. DESIGNATION OF JOINT EXHIBITS: The parties should consider designating a list of joint exhibits and should file any list of exhibits to be jointly designated by **September 28, 2016**.

17. PRETRIAL CONFERENCE: A pretrial conference shall be held at 10:30 a.m. on **September 22, 2016**, at the Clarksburg, West Virginia point of holding court. Lead trial counsel for each represented party must attend. Counsel and parties should be prepared to participate fully and to discuss all aspects of the case, including the matters set forth in the pretrial order. Persons with full authority to settle the case for each party shall be present in person.

18. TRIAL: A bench trial in this action shall be held on **October 3, 2016 at 9:00 A.M.** at the Clarksburg, West Virginia point of holding court. This case is presently the first case on the trial docket for that week.

19. SETTLEMENT AUTHORITY AND SANCTIONS: At least one of the attorneys for each party participating in any conference before trial shall have authority to make decisions as to settlement,

Novartis, etc., et al. v. Mylan, etc., et al.

1:14cv111

---

SCHEDULING ORDER

---

stipulations and admissions on all matters that participants reasonably anticipate may be discussed. Counsel and parties are subject to sanctions for failures and lack of preparation specified in Fed. R. Civ. P. 16(f) and L.R. Civ. P. 37.01 respecting pretrial conferences or orders.

20. **DEADLINES FINAL:** The time limitations set forth above shall not be altered except as set forth in L.R. Civ. P. 16.01(f).

All dates for submissions, deliveries and filings with the Clerk or the Court refer to the date the materials must be actually received not the mailing date.

**FAILURE ON THE PART OF COUNSEL TO APPEAR AT THE PRETRIAL CONFERENCE OR TO COMPLY WITH THE REQUIREMENTS OF THIS ORDER WILL SUBJECT THE PARTY OR ATTORNEY TO APPROPRIATE SANCTIONS UNDER THE RULES, AND MAY RESULT IN DISMISSAL OR STRIKING OF ALL PLEADINGS OF THE FAILING PARTY OR PERSON. COMPLIANCE WITH THIS ORDER INCLUDES *TIMELY AND GOOD FAITH EFFORT BY ALL PARTIES TO MEET AND JOINTLY PREPARE THE FINAL PRETRIAL ORDER AND OTHER ITEMS DESCRIBED ABOVE.***

It is so ORDERED.

Novartis, etc., et al. v. Mylan, etc., et al.

1:14cv111

---

SCHEDULING ORDER

---

The Court directs the Clerk to transmit copies of this Scheduling Order to counsel of record.

DATED: March 10, 2015

/s/ Irene M. Keeley  
IRENE M. KEELEY  
UNITED STATES DISTRICT JUDGE